REMARKS

The claims and specification referred to herein are from the published PCT application (WO2004/110317) corresponding to PCT/DK2004/000412. The specification has been amended to provide the relationship to previous applications, the claims of priority to said applications, and to reflect amendments made during prosecution of the PCT application. In the present paper, Claims 1-14 have been canceled, and new claims 15-28 have been added. Thus, claims 15-28 are presented for examination. Support for the new claims may be found in original claims 1-14, in the drawings and in the specification at, for example, page 3, lines 32 to page 8, line 18. Thus, the present amendments do not add new matter, and their entry is respectfully requested.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By:

Neil S. Bartfeld, Ph.D.
Registration No. 39,901
Agent of Record
Customer No. 20,995
(619) 235-8550

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121405

DEVICE FOR PREVENTING DISLOCATION OF HIP ARTHROPLASTY IMPLANTS

FIELD OF THE INVENTION

The invention relates to a method and a device for preventing dislocation of hip arthroplasty implants. The invention prevents dislocation by providing a restraining force on the femoral part of the implant under all movements of the leg. The invention further provides a method for mounting the device on a hip arthroplasty implant.

BACKGROUND OF THE INVENTION

In most western countries, the typical number of total hip joint arthroplasty every year lies between 0,5-1 ‰ of the population. World-wide an estimated number of 1 million people have a total hip joint arthroplasty every year (2003), with numbers increasing. Although total hip joint arthroplasty is a very successful orthopaedic surgical procedure, it suffers from a serious drawback, namely dislocation of the hip joint. Dislocation typically occurs after a wrong movement of the leg by the patient, whereby the femoral head is drawn out of the cup. The causes are many, e.g. wrong or imprecise placement of the arthroplasty components, looseness in the surrounding tissue, of failure on the patients side to follow the restrictions in movements following from the surgery.

Dislocation after a total hip joint arthroplasty is a common adverse effect for patients having hip arthroplasty implants. Surveys report that 3-5 % of the patients experience a dislocation at some point. However, numbers as high as 15% has been reported. A dislocation can occur at any time in the lifetime of the arthroplasty, with an increased risk within the first month after the operation. It is not only a nuisance for the patient, it is also a substantial economical burden to hospitals and insurance companies.

A number of measures have been taken to avoid dislocation, including modification of the components to try and make the arthroplasty more stable. However, any use of locking mechanisms between the femoral ball and the acetabular socket has been fraught with problems. Such constrained sockets fail early because of high stresses arising from impingement between the socket and femoral neck. This may cause the socket to pull out from the bone attachment in the pelvis, or dislodge the ring lock holding the devices together.

Collars for sealing joint prosthesis assemblies to prevent diffusion of e.g. debris or lubricants are well known from the prior art, e.g. FR 1416534, DE 3741490, US 4731088, US 5514182 or WO 00/57820. However, none of these provide any means for preventing dislocation of the joint prosthesis.

1A Insertion sheet

A number of flexible constraining devices have been suggested.

US 5,755,807 describes an implantable module for use with a prosthetic joint that utilises a bellows and bearing with a rotating seal for encapsulating the articulating members of the implant. The bellows and the bearing primarily serve the purpose of containing a

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restraining movements typically leading to those positions. Alternatively the device should provide a further extra securing of the femoral head in the cup at the positions where dislocations are likely to occur. Both these demands may be met by a device which

a) provides a restraining force opposing movements typically leading to positions where dislocations are likely to occur, and which

b) provides an extra securing force for holding the femoral head in the cup when the leg is at positions where dislocations are likely to occur.

The device according to present invention provides these functions whilst representing a substitution of the anatomic and physiologic fibrous capsule. In order not to reduce the freedom of movement of the patient's leg, the restraining and securing forces should preferably increase with the amplitude of the movement.

In this description, a hip arthroplasty implant comprises at least the following components, an acetabular cup to be mounted in the acetabular cavity of a pelvis, a femoral stem to be mounted in the proximal end of a femoral bone and having a femoral neck, and a femoral head to be mounted on the femoral neck and to be situated in a receiving cavity of the acetabular cup. These components will be referred to throughout the text.

In general, any movement of a physical object can be resolved into a translation of the object to obtain its new position followed by a rotation around a properly chosen axis to obtain its new orientation. In a similar fashion, any normal movement of a hip joint can be resolved into two rotations around perpendicular axes; a rotation around a first axis through the centre of the femoral neck followed by a rotation around a second axis through the centre of the femoral head, which axis is perpendicular to the first axis. In the present specification, rotation around the first axis is referred to as axial rotation, whereas rotation around the second axis is referred to as planar rotations (as the femoral neck spans a plane during this). Almost all movements of the leg include combinations of axial and planar rotations. The above description of hip joint movements is by no means the only possible choice, but serves to unambiguously define the scope of the present invention and can be used to describe all possible hip joint movements.

In a first aspect, the invention provides a device for preventing dislocation of a hip arthroplasty implant, the device comprising

~~- a tubular collar having a first open end having a first rim and a second open end having a second rim,~~

~~- first fastening means for fastening the first rim in fixed relation to and at least partly encircling the receiving cavity of the acetabular cup, and~~

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~~- second fastening means for fastening the second rim to the femoral neck,~~

~~the device being characterised in that the second fastening means is adapted to fasten the second rim in fixed relation to and at least partly circumventing the femoral neck to prevent longitudinal movement of the second rim along the femoral neck and rotational movement of the second rim around the femoral neck.~~

- a tubular collar for executing a restraining force opposing movements of the femoral bone leading to positions where dislocations can occur, the tubular collar being formed in an elastic material with openings and having a first end and a second end,

- first fastening means for fastening the first end in fixed relation to and at least partly encircling the receiving cavity of the acetabular cup, and

- second fastening means for fastening the second end in fixed relation to and at least partly circumventing the femoral neck to prevent longitudinal movement of the second end along the femoral neck and rotational movement of the second end around the femoral neck.

It is of importance that the second rim is fastened in fixed relation to the femoral neck and that it is fastened to at least partly circumvent the femoral neck. The fixed fastening means that the femoral neck can not rotate without twisting the collar. Thus, any movement involving axial rotations will twist the tubular collar and thereby also stretch it along its longitudinal axis. Thereby, the tubular collar will execute a force restraining the movement of the femoral neck and a force pulling the femoral head towards the receiving cavity of the cup. These forces arise because the longitudinal stretching generates a force which can be resolved into two perpendicular components. A first component is perpendicular to the neck and represents a force restraining the movement. A second component is parallel to the neck and represents a securing force for holding the femoral head in the cup (please refer to Figure 7). The twisting of the collar has another important property. If the movement involves only planar rotation, the collar is stretched in one side and slacked in the opposite side. However, as most movements of the leg involve both axial and planar rotations, the collar will be stretched/slacked and twisted at the same time. The twisting of the collar will tighten the slacked side of the collar whereby this part will also contribute with a securing force component. In the devices described in the prior art, the femoral neck can rotate freely, and the net/bellows are not twisted. Therefore, it is an important feature that the second rim is fastened n fixed relation to the femoral neck.

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As the forces work on the femoral neck, and not the head itself, it is important that they work on all sides of the neck at the same time. If not, the total resulting securing force component may be asymmetric resulting in a skew pull of the neck towards the cup. Therefore, it is an important feature that the second rim is fastened so as to at least partly circumvent the femoral neck. Preferably, the tubular collar, the rims and the fastenings means completely encircle the neck etc., however, for the purpose of mounting or assembling the device, it may be advantageous to have small open or incomplete sections.

The tubular collar may be a mesh woven in the form of an open stocking by e.g. cross-linked HMDPE fibres, polyethylene fibres, or fibres of other known biocompatible materials. The fabric of the mesh preferably consists of bioacceptable material. To provide the longitudinal stretching force, the tubular collar is preferably elastic in at least a longitudinal

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direction. The elasticity should be chosen so that the collar is stretched without tearing by the forces in play when the device is mounted on a grown up human being. Further, the tubular collar may be elastic in a radial direction. The elastic properties of the mesh are related to the weaving technique used in the fabric.

In alternative embodiments, the tubular collar may be formed by a ~~continuous~~ sheet or membrane of known, elastic biocompatible material such as artificial rubbers. The elastic material is preferably enforced to increase it strength and/or elasticity and/or providing a maximum stretching limit for the material. The tubular collar may also incorporate a bellows comprising metal springs. In all embodiments, the tubular collar preferably has the shape of a truncated cone.

The first and second fastening means preferably comprise first and second rings attached to the first and the second rim. The first ring may have one or more protrusions on, or incisions in, a first surface so that it can be assembled with a surface part of the acetabular cup, or with a flange to be fixed on the acetabular cup, having at least one corresponding incision or protrusion. There exist a large number of possible designs for attaching the first rim to the acetabular cup, all of which provide the essential feature of easy fixation using only biocompatible materials.

In a preferred embodiment, the second ring attached to the second rim has a slot for receiving a clamp formed as an open ring to be inserted in said slot. The femoral neck, or a flange to be fixed on the femoral neck, has an outer circumference with a shape corresponding to a shape of the inner circumference of said clamp. By mounting the second ring on the femoral neck (or the flange), the clamp can be inserted in the slot to fix the ring on the femoral neck.

Alternatively, the second ring may have one or more protrusions on or incisions in an internal circumference so that it can be mounted on the femoral neck, or a flange to be fixed on the femoral neck, having at least one corresponding incision or protrusion around its outer circumference.

This will allow for each of the end of the tubular collar to be fixed at several different positions so that the collar can be mounted in a position where it is not twisted.

In an alternative embodiment, the second fastening means comprises a ring attached to the second rim, which ring can be fixedly mounted around the femoral neck by shrink fitting. Alternatively, the second fastening means comprises a ring attached to the second rim, which ring can be fixedly mounted around the femoral neck by at least one bolt,

The ring 30 further has two or more holes 33 for screws or bolts to fix the ring 30 to the part 34. Figure 3B illustrates the ring 30 fastened on the acetabular cup 2 with screws 36.

Figure 4A-C illustrates a preferred embodiment of the second fastening means 25. The second fastening 25 consist of a ring 40 attached to the second, narrower rim 26 of the tubular collar 21. The ring 40 is to be fastened on the femoral neck 6. As shown in Figure 4B, a stationary flange 48 is fixated on the femoral neck 6. The flange 48 has incisions 49 representing the positions around the first axis 10 (see Figure 1) on which the collar 21 can be fastened. To fasten the ring 40 on the flange 49, the ring 40 is slit over the flange 49 at the desired position around the first axis. The second fastening also includes a locking clamp 44 shown in Figure 4C. The clamp 44 fits in a slot 42 in the ring 40 (see Figure 4A). The straight side parts of the clamp 44 fits the width of the slot 42, so that the clamp can be inserted in the slot without clearance. An outer perimeter of the flange 48 of Figure 4B fits an inner perimeter of the clamp 44. The clamp has a protrusion 46 on its inner perimeter corresponding to the incisions 49 in the flange. The clamp 44 also has a pin 45 for inserting and removing the clamp. The ring is locked in the desired position by insertion of the clamp 44 in the slot 42.

When the joint of the implant undergoes planar rotations, one side of the collar is stretched as illustrated in Figure 5. The side of the collar opposite to the stretched side will be slacked. If the collar is a mesh as shown in Figure 5, then stretching the collar means stretching individual strings in the mesh. As illustrated in Figure 7, the stretching of a string produces a stretching force $F_{stretch}$ having a component $F_{restrain}$ restraining the planar rotation and component F_{secure} pulling the femur towards the pelvis and thereby securing the femoral head in the cup. The same forces come into play if a ~~continuous~~ material such as an artificial rubber sheet forms the collar.

As described previously, axial rotations as illustrated in Figure 6 will twist the tubular collar because the femoral neck can not rotate without the collar. As the distance between the first and second fastening means 22 and 25 does not change, the twisting stretches the individual strings in the mesh, and thereby also the collar along its longitudinal axis. Thus, the forces of Figure 7 come into play as for the planar rotation of Figure 5.

When the movement is a combination of planar and axial rotations, as most normal movements are, the stretching/slacking of Figure 5 is combined with the twisting of Figure 6. Thus, the strings on both the stretched and the slacked side of Figure 5 will be stretched due to the twisting. Thereby, the strings on the slacked side will not be slacked, only less stretched than the strings on the stretched side. The force components $F_{restrain}$ and F_{secure} of Figure 7 will increase due to this combined effect, so that

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- the femoral head will be held even more securely in the cup, and
- the motion will be restrained even further, minimising the risk for the leg to move to a dislocating position.

Thus, the twisting of the collar enhances the anti-dislocation effect of the device.

As mentioned previously, the restraining and securing forces provided by the collar may increase with the amplitude of the movement. This will increase the freedom of movement of the leg for small amplitudes while increasing the restraining and securing forces for large amplitudes. The response of the collar depends on its elasticity, which depends on the applied material and the weave of the mesh.

The tubular collar of the device according to the invention may be embodied in many different ways, all providing the essential features. A large number of designs and materials may be applied. Figure 8 shows another design of a tubular collar 81 made from an enforced artificial rubber tubing with openings 82 for improving the mobility of the material upon axial rotations. The artificial rubber tubing may ~~also be intact with no holes or~~ have varying thickness or material properties to increase mobility.

The spring force from a typical metal spring will increase linearly with the distance in most of its dynamical range. This is illustrated by the curve 91 in the graph 90 Of Figure 9 having the spring/elastic force F along the principal axis and the distance d along the secondary axis. some deviation from the curve 91 will occur when the spring is close to fully stretched. Elastic materials such as e.g. artificial rubber have a different response. Here, the force increases nonlinearly with the distance of extension. Curve 92 in Figure 9 shows the response of a normal rubber band.

In a preferred embodiment, the tubular collar response with a force which increase nonlinearly with an amplitude of a movement of the femoral neck. In another embodiment, the tubular collar response with a force which increase at least substantially linearly with an amplitude of a movement of the femoral neck.

CLAIMS *as amended in response to interview pursuant to Rule 66.6 PCT*

1. A device for preventing dislocation of a hip arthroplasty implant (20), the hip arthroplasty implant comprising an acetabular cup (2) to be mounted in the acetabular cavity of a pelvis (3), a femoral stem (4) to be mounted in the proximal end of a femoral bone (5) and having a femoral neck (6), and a femoral head (7) to be mounted on the femoral neck and to be situated in a receiving cavity of the acetabular cup,

the device comprising

- a tubular collar (21) for executing a restraining force opposing movements of the femoral bone leading to positions where dislocations can occur, the tubular collar being formed in an elastic material with openings and having a first end (24) and a second end (27),

- first fastening means (22) for fastening the first end in fixed relation to and at least partly encircling the receiving cavity of the acetabular cup, and

- second fastening means (25) for fastening the second end in fixed relation to and at least partly circumventing the femoral neck to prevent longitudinal movement of the second end along the femoral neck and rotational movement of the second end around the femoral neck.

2. The device according to any of the preceding claims, wherein the tubular collar is elastic in at least a longitudinal direction.

3. The device according to any of the preceding claims, wherein the tubular collar is elastic in at least a radial direction.

4. The device according to any of the preceding claims, wherein the tubular collar is an elastic mesh.

5. The device according to any of the preceding claims, wherein the first fastening means comprises a ring (30) attached to the first end, the ring having one or more protrusions on or incisions (32) in a first surface, and wherein an accessible surface part (34) of the acetabular cup, or of a flange to be fixed on the acetabular cup, has at least one corresponding incision or protrusion (35).

6. The device according to any of the preceding claims, wherein the second fastening means comprises a ring (40) attached to the second end, the ring having one or more protrusions on or incisions in an internal circumference, and wherein the femoral neck or a flange (48) to be fixed on the femoral neck has at least one corresponding incision or protrusion (49) around its outer circumference.

7. The device according to any of claims 1 - 5, wherein the second fastening means comprises a ring (40) attached to the second end, the ring having a slot (42), and a clamp (44) formed as an open ring to be inserted in said slot, and wherein the femoral neck or a flange (48) to be fixed on the femoral neck, has an outer circumference with a shape corresponding to a shape of the inner circumference of said clamp.

8. A method for stabilisation of a hip arthroplasty implant with a device for preventing dislocation of the hip arthroplasty implant,

the hip arthroplasty implant comprising an acetabular cup mounted in the acetabular cavity of a pelvis, a femoral stem mounted in the proximal end of a femoral bone and having a femoral neck, and a femoral head to be mounted on the femoral neck and to be situated in a receiving cavity of the acetabular cup,

the device for preventing dislocation comprising an elastic tubular collar having a first end to be mounted in fixed relation to and at least partly encircling the receiving cavity of the acetabular cup, and a second end to be mounted in fixed relation to and at least partly circumventing the femoral neck,

the method preventing dislocation of the hip arthroplasty implant by the steps of

- providing a joint of a hip implant in a neutral position with a tubular collar being fixedly mounted, and
- moving the joint of the hip implant away from the neutral position,
- executing a force restraining the movement of the femoral neck and a force pulling the femoral head towards the receiving cavity of the acetabular cup.

9. The method according to claim 8, wherein the movement of the joint is chosen from a group of movements containing:

- flexion movement in a sagittal plane,
- extension movement in a sagittal plane,
- adduction movement in a frontal plane,
- abduction movement in a frontal plane,
- external rotation in a transverse plane,
- internal rotation in a transverse plane,

and any combination thereof.

10. The method according to claim 8, wherein the movement of the joint is chosen from:

- axial rotation around a longitudinal axis of the femoral neck,
- planar rotations where the angle between the femoral neck and the acetabular cup changes,
- combinations of axial and planar rotations, and
- any translation.

11. The method according to claim 8, wherein the force restraining the movement of the femoral neck increase proportionally to an amplitude of the movement.

12. The method according to claim 8, wherein the force restraining the movement of the femoral neck increase nonlinearly with an amplitude of the movement.

13. A method for mounting an device for preventing dislocation on a hip arthtoplasty implant,

the hip implant comprising an acetabular cup mounted in the acetabular cavity of a pelvis, a femoral stem mounted in the proximal end of a femoral bone and having a femoral neck, and a femoral head to be mounted on the femoral neck and to be situated in a receiving cavity of the acetabular cup,

the device for preventing dislocation comprising

- a tubular collar having a first end and a second end, the tubular collar being elastic in at least a longitudinal direction,
- first fastening means for fastening of the first end at least partly encircling the receiving cavity of the acetabular cup, and
- second fastening means for fastening of the second end in fixed relation to and at least partly circumventing the femoral neck,

the method comprising the steps of:

- mounting the tubular collar to the femoral neck and positioning the femoral head in the acetabular cup with the leg containing the femoral stem situated anatomically,
- positioning the leg in a neutral position,
- fastening the first end in fixed relation to and encircling the receiving cavity of the acetabular cup with the first fastening means,
- fastening the second end in fixed relation to and circumventing the femoral neck with the second fastening means,

wherein the steps of fastening the first or second end with the first or second fastening means, respectively, comprises the step of uniformly tightening or stretching the tubular collar, so that the tubular collar during movement of the leg exerts a force restraining the movement of the femoral neck and a force pulling the femoral head towards the receiving cavity of the acetabular cup.

14. The method according to claim 13, wherein the step of applying the tubular collar to the hip arthroplasty implant comprises the steps of mounting the tubular collar on the femoral neck so that the second end encircles of the femoral neck and thereafter mounting the femoral head on the femoral neck.